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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,885	03/15/2000	Michael L. Nuccio	4300.012700	9507

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/525,885

Applicant(s)

NUCCIO ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 39-42, 77-83, 94, 95 and 98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 98 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13, 39-42, 77-83, 94 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

The Request for Continued Examination filed September 25, 2003 has been received and entered. In addition, the request for 3 month suspension is also noted, wherein the time for suspension ended on December 25, 2003. Applicants' representative asserted that the Examiner would be contacted for an interview prior to the next office action. However, no interview has been scheduled and the application is due for examination. Applicants' representative is invited to contact the Examiner upon receipt of the present office action to schedule an interview.

Claims 1-13 and 39-40 have been newly amended.

Claims 14-36, 84-93 and 96-97 are cancelled. Please note that on the present copy of the claims many of the cancelled claims are labeled "withdrawn". Correction is required.

Claims 1-13, 39-42, 77-83, 94, 95 and 98 are pending and are examined on the merits.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 1-7, 9-13, 39-42, 77-83, 94 and 95 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

3. Claims 1-7, 9-13, 39-42 77-83, 94 and 95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for one sequence from spinach, designated PEAMT (encoding SEQ ID NO: 2), that has PEAMT activity (see pages 90-91 of the specification), does not reasonably provide enablement for any gene that encodes an enzyme the exhibits PEAMT activity that comprises at least 27 contiguous amino acids of SEQ ID NO: 2 or is at least 85% identical to SEQ ID NO: 2, for the reasons set forth in the last office action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

4. Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive. Applicants assert that there are many practical uses for the claimed DNA segments outside of the production of enzymatically-active proteins, and the standard is that the skilled artisan must be able to make and use the DNA segments without undue experimentation. The Examiner disagrees in that the claims are drawn to a polynucleotide that encodes a polypeptide having S-adenosyl-L-methionine:phosphoethanolamine N-methyltransferase activity that may be as small as 27 contiguous amino acids of SEQ ID NO: 2 or has at least about 85% sequence identity to SEQ ID NO: 2. Therefore, the claims require

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that the claimed polynucleotides encode a polypeptide having S-adenosyl-L-methionine:phosphoethanolamine N-methyltransferase activity. However, the specification does not provide examples or guidance with regard to which polynucleotide fragments would meet this requirement. Furthermore, the how to use standard for 112, first paragraph is different than the utility standard under 101.

Applicants further argue that claims directed to a polynucleotide that encodes a polypeptide derived from S-adenosyl-L-methionine:phosphoethanolamine N-methyltransferase activity are also enabled, since these polypeptides may be used in various embodiments that do not require the enzymatic activity. Applicants assert that the specification "exhaustively teaches how to make and use" these compositions, and therefore, only routine experimentation would be required to practice these embodiments. As stated above, the Examiner maintains that the claims are drawn to a polynucleotide that encodes a polypeptide having S-adenosyl-L-methionine:phosphoethanolamine N-methyltransferase activity, yet the specification does not provide examples or guidance with regard to which polynucleotide fragments would meet this requirement. Thus, for the reasons set forth in the last office action, it would require undue experimentation to make and/or use the claimed invention.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Elizabeth F. McElwain
Ph.D. Level Examiner
Art Unit 1638

EFM